Arnold B. Calmann
Katherine A. Escanlar
One Gateway Center, 9th Floor
Newark, NJ 07102-5308
T: (973) 622-3333
abc@saiber.com
kescanlar@saiber.com

Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC., Plaintiff, v. AMNEAL PHARMACEUTICALS, LLC, Defendant.	CIVIL ACTION NO.: _____

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant Amneal Pharmaceuticals LLC ("Amneal"), Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity"), by and through its attorneys, alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent Nos. 10,695,329 ("the '329 patent"), 10,799,453 ("the '453 patent"), 10,894,039 ("the '039 patent"), and 10,952,998 ("the '998 patent") (collectively, the "Katerzia Patents"), arising under the patent laws of the United States, Title 35, United States Code. This action arises out of the filing by Amneal of Abbreviated New Drug Application ("ANDA") No. 215035 with the U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Azurity's oral liquid formulation that is the subject of New Drug Application ("NDA") No. 211340, hereinafter referred to as Azurity's "Katerzia® product." Azurity seeks all available relief under the patent

laws of the United States, 35 U.S.C. § 100 *et. seq.*, and other applicable laws for Amneal's infringement of the Katerzia Patents.

The Parties

2. Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, Massachusetts, 01801.

3. On information and belief, Amneal is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, NJ 08807-2863. On information and belief, Amneal is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the U.S. market.

Jurisdiction and Venue

4. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338(a) (patent infringement). Relief is sought under 35 U.S.C. § 271(e).

5. This Court has personal jurisdiction over Amneal because, on information and belief, Amneal is a limited liability company operating a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, NJ 08807-2863.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Azurity's Katerzia® Product

7. Azurity's Katerzia® product is an FDA approved and labeled calcium channel blocker indicated for treatment of hypertension in adults and pediatric patients 6 years of age and older. Katerzia® is also indicated for treatment of coronary artery disease, including chronic

stable angina, vasospastic angina, and angiographically documented coronary artery disease in patients without heart failure or an ejection fraction < 40%.

8. Azurity is the holder of approved NDA No. 211340.

Patents-In-Suit

9. The '329 patent, entitled "Amlodipine Formulations," was duly and legally issued on June 30, 2020. A true and correct copy of the '329 patent is attached to this Complaint as Exhibit A.

10. The face of the '329 patent names Scott Brauer and Gerold L. Mosher as inventors and Silvergate Pharmaceuticals, Inc. ("Silvergate") as assignee. Silvergate assigned all interest in the '329 patent to Azurity. Azurity, as assignee, holds all rights to sue and to recover for infringement of the '329 patent.

11. Pursuant to 21 U.S.C. § 355, the '329 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), in connection with Azurity's Katerzia® product.

12. Azurity's Katerzia® product is covered by at least one claim of the '329 patent.

13. The '453 patent, entitled "Amlodipine Formulations," was duly and legally issued on October 13, 2020. A true and correct copy of the '453 patent is attached to this Complaint as Exhibit B.

14. The face of the '453 patent names Scott Brauer and Gerold L. Mosher as inventors and Silvergate as assignee. Silvergate assigned all interest in the '453 patent to Azurity. Azurity, as assignee, holds all rights to sue and to recover for infringement of the '453 patent.

15. Pursuant to 21 U.S.C. § 355, the ’453 patent is listed in the Orange Book in connection with Azurity’s Katerzia® product.

16. Azurity’s Katerzia® product is covered by at least one claim of the ’453 patent.

17. The ’039 patent, entitled “Amlodipine Formulations,” was duly and legally issued on January 19, 2021. A true and correct copy of the ’039 patent is attached to this Complaint as Exhibit C.

18. The face of the ’039 patent names Scott Brauer and Gerold L. Mosher as inventors and Silvergate as assignee. Silvergate assigned all interest in the ’039 patent to Azurity. Azurity, as assignee, holds all rights to sue and to recover for infringement of the ’039 patent.

19. Pursuant to 21 U.S.C. § 355, the ’039 patent is listed in the Orange Book in connection with Azurity’s Katerzia® product.

20. The use of Azurity’s Katerzia® product is covered by at least one claim of the ’039 patent.

21. The ’998 patent, entitled “Amlodipine Formulations,” was duly and legally issued on March 23, 2021. A true and correct copy of the ’998 patent is attached to this Complaint as Exhibit D.

22. The face of the ’998 patent names Scott Brauer and Gerold L. Mosher as inventors and Silvergate as assignee. Silvergate assigned all interest in the ’998 patent to Azurity. Azurity, as assignee, holds all rights to sue and to recover for infringement of the ’998 patent.

23. Pursuant to 21 U.S.C. § 355, the ’998 patent is listed in the Orange Book in connection with Azurity’s Katerzia® product.

24. Azurity's Katerzia® product is covered by at least one claim of the '998 patent.

Infringement by Amneal

25. By letter dated February 23, 2021 (the "Notice Letter"), Amneal notified Azurity that it had submitted ANDA No. 215035 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. §314.95(c)(1)) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Azurity's Katerzia® product (the "Amneal ANDA Product") before the expiration of the '329 and '453 patents.

26. On information and belief, Amneal is seeking FDA approval to engage in the commercial manufacture, use, and sale of the Amneal ANDA Product before the expiration of the '329. '453, '039 and '998 patents.

27. On information and belief, Amneal intends to engage in commercial manufacture, use, and sale of the Amneal ANDA Product promptly upon receiving FDA approval of its ANDA.

28. By filing ANDA No. 215035, Amneal has necessarily represented to FDA that the Amneal ANDA Product has the same active ingredient as Azurity's Katerzia® product, as well as the same dosage form, route of administration, use, and strength as Azurity's Katerzia® product, and that it is bioequivalent to Azurity's Katerzia® product.

FIRST COUNT

Infringement of the '329 Patent Under 35 U.S.C. § 271 (e)(2)(A)

29. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

30. Amneal submitted ANDA No. 215035 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or

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